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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,220	04/17/2008	Catherine Ronin	BJS-1487-29	5743

23117 7590 01/11/2010  
NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER
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HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,220	<b>Applicant(s)</b> RONIN ET AL.	
	<b>Examiner</b> PHUONG HUYNH	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 114-130 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 114-130 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/25/09; 8/2/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 114-130 are pending.
2. The objection to claim 101 for misspelling has been obviated by the claims amendment filed September 25, 2009.
3. The objection to claims 104-105, and 112-113 has been obviated by the claims amendment filed September 25, 2009.
4. The new matter rejection of claims 101-113 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention has been obviated by the claims amendment filed September 25, 2009.
5. The rejection of claims 110-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been obviated by the claims amendment filed September 25, 2009.
6. The rejection of claims 101-108 and 110-112 under 35 U.S.C. 103(a) as being unpatentable over Papandreou et al (Molecular and Cellular Endocrinology 73: 15-26, 1990; PTO 1449) in view of Kashiwai et al (J Immunological Methods 143: 25-30, 1991; PTO 1449), Schaaf et al (Molecular and Cellular Endocrinology 132: 185-194, 1997; PTO 1449), and Szkudlinski et al (Endocrinology 133(4): 1490-1503, 1993; PTO 1449) has been obviated by the claims amendment filed September 25, 2009.
7. The rejection of claim 109 under 35 U.S.C. 103(a) as being unpatentable over Papandreou et al (Molecular and Cellular Endocrinology 73: 15-26, 1990; PTO 1449) in view of Kashiwai et al (J Immunological Methods 143: 25-30, 1991; PTO 892), Schaaf et al (Molecular and Cellular Endocrinology 132: 185-194, 1997; PTO 1449) and Szkudlinski et al (Endocrinology 133(4):

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1490-1503, 1993; PTO 1449) as applied to claims 101, 103-108 and 110-112 mentioned above and further in view of Legaingneur et al (J Biol Chem 276(24): 21608-21617, 2001; PTO 1449) has been obviated by the claims amendment filed September 25, 2009.

8. The rejection of claim 113 under 35 U.S.C. 103(a) as being unpatentable over Papandreou et al (Molecular and Cellular Endocrinology 73: 15-26, 1990; PTO 1449) in view of Kashiwai et al (J Immunological Methods 143: 25-30, 1991; PTO 892), Schaaf et al (Molecular and Cellular Endocrinology 132: 185-194, 1997; PTO 1449), and Szkudlinski et al (Endocrinology 133(4): 1490-1503, 1993; PTO 892) as applied to claims 101, 103-108 and 110-112 mentioned above and further in view of Zerfaoui et al (Eur J Clin Chem Clin Biochem 34: 749-753, 1996; PTO 1449) and Fionnuala et al (Molecular Biotechnology 12: 203-206, 1999; PTO 1449) has been obviated by the claims amendment filed September 25, 2009.
9. New grounds of objections and rejection are set forth below.
10. Claim 114 is objected to because the punctuation mark "," is missing between "first glycoprotein" at line 3 and "said first glycoprotein" at line 4.
11. Claim 119 is objected to because "lentil ." should have been "lentil." Further, the phrase "a less fucosylated glycoform of the second glycoprotein as compared to the second glycoprotein" is indefinite because the second glycoprotein is less fucosylated to begin with, it is unclear what is being compared to. It is suggested that claim 119 be amended to recite "The process according to claim 115, wherein the less fucosylated glycoform of recombinant human TSH is obtained by lentil fractionation and collecting a fraction which does not bind to lentil."
12. Claim 121 is objected to because the phrase "a more sialylated glycoform of the second glycoprotein as compared to the second glycoprotein" is indefinite because the second glycoprotein is already more sialylated to begin with, it is unclear what is being compared to, i.e., more sialylated glycoform of the second glycoprotein as compared to the already more sialylated second glycoprotein? It is suggested that claim 121 be amended to recite "The process according to claim 114, wherein the more sialylated glycoform of the recombinant human TSH is obtained

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by sialyltransferase treatment or by neuraminidase treatment followed by sialyltransferase treatment.

13. Claim 123 is objected to because “deleted of at most”. It is suggested that claim 123 be amended to recite “The process according to claim 122, wherein said  $\alpha$ -2,6-sialyltransferase is a N-terminally shortened ST6Gall sialyltransferase having its first 99 residues deleted as set forth in SEQ ID NO: 1.
14. Claims 124-125 and 128 are objected to under 37 CFR 1.75(C), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Specifically, claim 124 fails to further limit the subject matter of the previous claim 115. Claim 124 recites “The process according to claim 115, wherein, in a *step preceding* the step of determination of binding ....” The previous claim 115 comprises just the step of determination of antibody having higher binding affinity for recombinant human TSH having more sialylated, more branched and less fucosylated or the recombinant human TSH being more sialylated, less branched and less fucosylated as compared to either blood human TSH or pituitary human TSH. Thus, claim 124 does not limit the subject matter of the previous claims 115 and 114. Likewise, the “in a first step said preceding the preliminary step” in claim 125 does not limit the subject matter of the previous claims 115 and 114. Finally, Claim 128 does not limit the subject matter of the previous because there is no preliminary step in base claims 126, 127 and 114.
15. Claim 128 is objected to because it is unclear as to what is “onto a support” at line 7.
16. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
17. Claims 120 and 125 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The “ConA fractionation” in claim 120 has no antecedent basis in base claim 115 because the word “ConA fractionation” is not recited in claim 115.

The “said preceding the preliminary step” in claim 125 has no antecedent basis in the base claim 115 because “preliminary step” is not recited in claim 124.

18. Claims 114-130 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

- contacting a panel of antibodies elicited against the pituitary or blood human TSH with at least one glycoform specific recombinant human TSH wherein the recombinant human TSH is either more sialylated, more branched and less fucosylated or more sialylated, less branched and less fucosylated,
- determining the binding affinity of the antibodies between the pituitary or blood human TSH and at least one glycoform specific recombinant human TSH having more sialylated, more branched and less fucosylated or recombinant human TSH having more sialylated, less branched and less fucosylated, and
- recovering the antibodies having higher binding affinity for the specific recombinant human TSH having more sialylated, more branched and less fucosylated or the recombinant human TSH having more sialylated, less branched and less fucosylated as compared to the pituitary or blood human TSH.

Claims 115-130 are included in this rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

19. No claim is allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9:00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The IFW official Fax number is (571) 273-8300.
22. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/

Primary Examiner, Art Unit 1644

December 31, 2009